DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-11-0058; NOP-11-09PR]

RIN 0581-AD15

National Organic Program; Proposed Amendments to the National List of Allowed and Prohibited Substances (Crops, Livestock and Processing).

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the U.S. Department of Agriculture's (USDA's) National List of Allowed and Prohibited Substances (National List) to reflect recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on October 28, 2010, and April 29, 2011. The recommendations addressed in this proposed rule pertain to changing the annotation for one substance, tetracycline, currently allowed for use in organic crop production, and adding two substances, formic acid and attapulgite, along with any restrictive annotations, for use in organic livestock production and organic processing, respectively.

DATES: Comments must be received by (INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER).

ADDRESSES: Interested persons may comment on the proposed rule using the following procedures:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

- Mail: Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW, Room 2646-So., Ag Stop 0268, Washington, DC 20250-0268.

Instructions: All submissions received must include the docket number AMS-NOP-11-0058; NOP-11-09PR, and/or Regulatory Information Number (RIN) 0581-AD15 for this rulemaking. You should clearly indicate the topic and section number of this proposed rule to which your comment refers. You should clearly indicate whether you support the action being proposed for the substances in this proposed rule. You should clearly indicate the reason(s) for your position. You should also supply information on alternative management practices, where applicable, that support alternatives to the proposed action. You should also offer any recommended language change(s) that would be appropriate to your position. Please include relevant information and data to support your position (e.g. scientific, environmental, manufacturing, industry, impact information, etc.). Only relevant material supporting your position should be submitted. All comments received will be posted without change to http://www.regulations.gov.

Document: For access to the document to read background documents or comments received, go to http://www.regulations.gov. Comments submitted in response to this proposed rule will also be available for viewing in person at USDA-AMS, National Organic Program, Room 2646-South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720-3252.

FOR FURTHER INFORMATION CONTACT: Melissa Bailey, Ph.D., Director, Standards Division, Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFROMATION:

I. Background

On December 21, 2000, the Secretary established, within the National Organic Program (NOP) (7 CFR part 205), the National List regulations §§ 205.600 through 205.607. This National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990, as amended, (7 U.S.C. 6501 et seq.), (OFPA), and NOP regulations, in § 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling be on the National List.

Under the authority of the OFPA, as amended (7 U.S.C. 6501-6522), the National List can be amended by the Secretary based on recommendations developed by the NOSB. Since established, the NOP has published multiple amendments to the National List: October 31, 2003 (68 FR 61987); November 3, 2003 (68 FR 62215); October 21, 2005 (70 FR 61217); June 7, 2006 (71 FR 32803); September 11, 2006 (71 FR 53299); June 27, 2007 (72 FR 35137); October 16, 2007 (72 FR 58469); December 10, 2007 (72 FR 69569); December 12, 2007 (72 FR 70479); September 18, 2008 (73 FR 54057); October 9, 2008 (73 FR 59479); July 6, 2010 (75 FR 38693); August 24, 2010 (75 FR

51919), December 13, 2010 (75 FR 77521); and March 14, 2011 (76 FR 13501). Additionally, proposed amendments to the National List were published on November 8, 2010 (75 FR 68505) and on May 5, 2011 (76 FR 25612).

This proposed rule would amend the National List to reflect three recommendations submitted to the Secretary by the NOSB on October 28, 2010, and April 29, 2011. Based upon their evaluation of petitions submitted by industry participants and review of technical reports, the NOSB recommended that the Secretary revise the annotation for one substance (tetracycline) for organic crop production on § 205.601, add one substance (formic acid) to § 205.603(b) for organic livestock production, and add one substance (attapulgite) to § 205.605(a) for organic processing. The exemptions for use of each substance in organic production were evaluated by the NOSB using the criteria specified in OFPA (7 U.S.C. 6517-6518).

II. Overview of Proposed Amendments

The following provides an overview of the proposed amendments to designated sections of the National List regulations:

Section 205.601 Synthetic substances allowed for use in organic crop production.

This proposed rule would amend § 205.601 by changing the annotation at paragraph (i)(12) to add an expiration date and specify the permitted use for the following substance:

Tetracycline. Tetracycline, in the form of oxytetracycline calcium complex, was included in the National List as originally published on December 21, 2000 (FR 65 80548), for use for fire blight control only. Tetracycline is a broad-spectrum antibiotic for control of bacteria, fungi and mycoplasma-like organisms which functions by

inhibiting protein synthesis in bacteria and altering bacterial membranes so that vital genetic material is leaked. For regulatory purposes, Environmental Protection Agency (EPA) uses the term oxytetracycline to refer to pesticides containing either calcium oxytetracycline or hydroxytetracycline monohydrochloride (oxytetracycline hydrochloride). Oxytetracycline is registered with the EPA for the following agronomic uses: fire blight of apples, pears, peaches and nectarines; pear decline; bacterial spot on peaches and nectarines; lethal yellowing of coconut palm; and lethal decline of pritchardia palm.

Oxytetracyclines are derived from the soil bacteria, Streptomyces, by a fermentation process. Technical grade tetracycline is a pale yellow to tan crystalline powder, is freely soluble in water, and decomposes above 180 degrees Celsius. Formulated products containing the technical grade oxytetracycline calcium complex and oxytetracyline hydrochloride for fireblight are wettable powders which are spray-applied using ground or aircraft equipment on foliage at early bloom stage, when fire blight infection usually occurs. Application may also occur by injection into the tree trunks using an injection device and an aqueous solution of oxytetracycline calcium and/or oxytetracycline hydrochloride. In addition to agronomic uses, oxytetracyclines are also antibiotics used in human and animal drugs to treat bacterial diseases.[1]

On July 6, 2010, AMS published a final rule (75 FR 38693), amending the listing for tetracycline to allow the use of another form of tetracycline, oxytetracycline hydrochloride, and adding an expiration date of October 21, 2012, in accordance with the NOSB November 2008 recommendation. In October 2010, a petition was submitted

[1] Technical Report on Tetracycline (oxytetracycline). April 1, 2011. Available in petitioned substances database, under "T," at the NOP website : www.ams.usda.gov/nop

requesting the removal of the October 21, 2012 expiration date. In effect, the petitioner requested an allowance for the use of tetracycline to control fire blight in apples and pears beyond the substance's current expiration date.

The NOSB Crops Committee reviewed the October 2010 petition to remove the expiration date from the current tetracycline annotation and initially issued a Committee proposal against the petitioner's request. The Committee referenced their concerns over antibiotic resistance and availability of fire blight resistant varieties as alternatives to tetracycline use as the basis for their proposal.[2] This proposal would have, in effect, retained the October 21, 2012 expiration date for tetracycline, after which the substance could no longer be used in organic crop production.

At its April 26-29, 2011, meeting in Seattle, WA, the NOSB received public comment on the Crops Committee's proposal to reject the petitioner's request. During the meeting, the NOSB discussed and received comments on potential alternatives to tetracycline, the challenges with the efficacy and adoption of those alternative strategies, and the potential impact of not allowing tetracycline for fire blight control after October 2012. Many commenters discussed the scope and availability of alternative methods for fire blight control including the use of fire blight resistant root stocks, biological controls, streptomycin, and apple and pear varieties that are less susceptible to fire blight. Comments from producers and researchers informed the NOSB that fire blight resistant root stocks and some biological controls are not yet commercially available.[3] These commenters also stated that the efficacy of commercially available biological control

[2] NOSB Crops Committee Recommendation on Tetracycline. April 2011. Available at the NOP website: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089511&acct=nosb

[3] Transcript from the April 26-29, 2011 NOSB meeting is available under the NOSB section of the NOP website at: http://www.ams.usda.gov/nop

products is inconsistent in reducing disease incidence, thus discouraging producers from using these products instead of tetracycline. Comments further described widespread pathogen resistance to streptomycin in certain areas of the country, such as the Pacific Northwest, which has decreased its effectiveness against fire blight. Commenters stated that this resistance to streptomycin has prompted some producers to use tetracycline as an alternative. In addition, the NOSB was informed that consumer demand is linked to apple and pear varieties which are more susceptible to fire blight. Growers in Washington State produced 88% of organic apples and 79% of organic pears harvested in the U.S. in 2008, and cultivars accounting for the highest proportion of this production are highly or moderately susceptible to fire blight.[4,5] The petitioner also commented that at least 38 of 50 organic apple and pear producers surveyed in Washington State felt that if the exemption for the use of tetracycline was allowed to expire on October 21, 2012, then they would be forced to reduce their acreage of susceptible varieties or exit the organic apple and pear production industry.[6]

Based upon the public comments, the NOSB Crops Committee revised their proposal at the April 2011 NOSB meeting and recommended extending the allowance for the use of tetracycline to control fire blight in apples and pears until October 21, 2014. The NOSB voted on and issued a final recommendation in support of this proposal. The NOSB concluded that use of tetracycline should be permitted to continue through

[4] U.S. Department of Agriculture, National Agricultural Statistics Service. 2007 Census of Agriculture: Organic Production Survey: Organic Fruit and Tree Nuts Harvested from Certified Organic Farms, Table 24, 2008. Available at: http://www.agcensus.usda.gov/Publications/2007/Online_highlights/Organics/ORGANICS.pdf.

[5] The petition was submitted by the Washington State Horticultural Association, and is available from the NOP website in the Petitioned Substances Database, http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase.

[6] Summarized from 2010 survey of organic apple and pear growers in Washington State: *Organic Orchards: Needs and Priorities*, conducted by David Granatstein (WSU-CSANR), Mark LaPierre, Wilbur-Ellis Co., and Nadine Lehrer, WSU-TFRC.

October 21, 2014, as options for biological controls and resistant varieties and rootstocks are further developed for commercial use. In their recommendation, the NOSB specified that the annotation include language to convey that the use of tetracycline is limited to apples and pears. The addition of "apples and pears" in the annotation accurately identifies the allowed use of this substance in organic production and would not change current use patterns.

The NOSB recommendation also stated that the Board expects the industry to make progress in the development of alternatives for fire blight control. The NOSB recommendation conveyed this expectation in stating that, "members of the industry will collaborate and coordinate efforts in preparing for the eventual removal of this material from the National List, specifically optimizing the use of resistant rootstocks and cultivars, preventive management methods, and the use of alternative, allowed biological and chemical controls whenever warranted."[7]

In response to the requests by the NOSB and the industry for additional resources to support research on alternatives to tetracycline in organic production, the NOP issued requests to the USDA Agricultural Research Service and the National Institute of Food and Agriculture in May of 2011 for assistance in prioritizing research in the following areas: (1) the efficacy of combinations of substances for fire blight management; (2) breeding, production, and propagation of resistant cultivars and rootstocks that are commercially viable; and (3) cultural practices, crop management, disease forecasting and other production practices that can optimize control of this disease.[8]

[7] NOSB Formal Recommendation on Tetracycline. April 29, 2011. Available at the NOP website: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5091701

[8] May 2011 Letters submitted by NOP to USDA ARS and NIFA on fire blight research. Available at the NOP website: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5091325

The Secretary has reviewed and proposes to accept the NOSB's recommendation. This proposed rule would amend § 205.601(i)(12) of the National List by: (1) inserting the qualifying words "in apples and pears"; between the words "control" and "only," in the current annotation and (2) replacing the current expiration date of "October 21, 2012" with the new expiration date, "October 21, 2014," after which tetracycline may not be used in organic apple and pear crop production for fire blight control.

Section 205.603 Synthetic substances allowed for use in organic livestock production.

This proposed rule would amend § 205.603 by redesignating current paragraphs (b)(2) through (b)(7) as paragraphs (b)(3) through (b)(8) for the purpose of adding the following substance as an external parasiticide at (b)(2):

Formic acid (CAS # 64-18-6). Formic acid was petitioned for use in May 2010, as a pesticide for suppression of Varroa mites[9]. Varroa mites attach themselves to the abdomens of bees and extract fluids from the circulatory system, causing the bees to weaken and die. Infestations can quickly destroy a hive and spread easily to nearby hives. Formic acid is a colorless liquid with a pungent odor which is miscible in water. This substance is the simplest carboxylic acid and is naturally occurring in small amounts in some insects and plants and is a natural component of honey. The manufacturing process for formic acid begins with the hydrolysis of methyl formate. Methanol and carbon monoxide are combined along with a strong base to produce methyl formate, which is then hydrolyzed to produce formic acid.[10] Formic acid is considered corrosive to metals and biological tissue, and occupational exposure to these fumigant products can

[9] The petition was submitted by the Hawaii Department of Agriculture, and is retrievable from the NOP website in the Petitioned Substances Database: http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase.

[10] Hazardous Substances Data Bank (HSDB). 2010. Formic Acid, CASRN: 64-18-6. Last revised 4-27-2010. Retrieved February 15, 2011, from http://toxnet.nlm.nih.gov.

cause eye, skin, and mucosal irritation.[11] This can be mitigated by the use of personal protective equipment. Fumigant mite control products for beehives generally consist of a gel pad impregnated with formic acid which is contained in a sealed plastic pouch. Application consists of cutting vents in the pouch and setting it in the hive, where it releases vapors that diffuse throughout the hive. The volatilization of formic acid causes mite deaths by asphyxiation generally without harm to exposed bees. It can also penetrate capped cells and sealed brood cells where mites are feeding.[12]

The use of synthetic formic acid is regulated by other Federal agencies. Formic acid has antibacterial properties that make it effective as a preservative, and the Food and Drug Administration (FDA) permits its use as a food additive in the feed and drinking water of animals (21 CFR 573.480). FDA also permits the use of formic acid as flavoring agent in processed foods (21 CFR 172.515). The Environmental Protection Agency (EPA) has exempted synthetic formic acid from the requirement of a tolerance in or on honey and honeycomb when used to control tracheal mites and suppress Varroa mites in bee colonies, and applied in accordance with label use directions (40 CFR 180.1178).[13] The EPA has examined the potential for formic acid residues to appear in beeswax and honey and concluded that residues above those found naturally are not expected when a formic acid pesticide product is used as directed.[14] Synthetic formic acid is currently permitted in Canada and the European Union for use in organic apiculture to control parasitic mites.

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[11] NOAA (CAMEO Chemical), 2011. Formic Acid, Retrieved February 15, 2011 from http://cameochemicals.noaa.gov/chemical/3513

[12] Technical Report on Formic acid. June 1, 2011. Available in petitioned substances database, under "F," at the NOP website : www.ams.usda.gov/nop

[13] Tracheal mites lay eggs inside bees' tracheal tubes, and their larvae feed on the bee after the eggs hatch.

[14] EPA, 2010. Formic Acid (214900) Fact Sheet, Retrieved February 15, 2011, from http://www.epa.gov/oppbppd1/biopesticides/ingredients/factsheets/factsheet_214900.htm.

At its October 25-28, 2010, meeting in Madison, WI, the NOSB recommended adding formic acid to the National List for use in organic livestock production solely as a pesticide within honeybee hives. The NOSB evaluated formic acid against the evaluation criteria of 7 U.S.C. 6517 and 6510 of the OFPA and received public comment at this meeting.[15] During the NOSB deliberations, the Board noted that they had not received any public comments against the addition of formic acid to the National List. The NOSB deliberations over the petition for this substance heavily relied upon the information provided by the petitioner. According to the formic acid petition, there are several methods for controlling mite populations in honeybee hives. These methods include those that are mechanical (e.g. trapping) and biochemical such as the use of synthetic sucrose octanoate esters (currently listed on § 205.603) for control for Varroa mites. However, data was provided by the petitioner illustrating that the allowed biochemical and mechanical control methods do not have the same efficacy as formic acid in the climatic conditions in Hawaii, one of the U.S.'s highest-producing organic honey regions.[16] The information presented by the petitioner and considered by the NOSB is generally supported by a June 2011 technical report for formic acid that the NOSB Livestock Committee accepted as sufficient.

During their deliberations, the NOSB also considered formic acid in the context of their final recommendations for apiculture standards from 2001 and 2010 and feedback from the Apiculture Working Group. Based upon their review of this information, the

[15] The record contains acknowledgement that the Board had requested a Technical Report for formic acid. However, this report was not available for review by the October 2010 meeting. The NOSB stated that, based on the information contained in the petition, they concluded that the substance is consistent with the OFPA evaluation criteria.

[16] Transcripts from the April 26-29, 2011 meeting can be retrieved from the NOSB section of the NOP webpage.

NOSB issued a final recommendation to add formic acid to the National List at § 205.603(b) with an annotation that would limit the substance's use to a pesticide solely within honeybee hives. In their recommendation, the NOSB did not limit the use of formic acid only for treatment of Varroa mites, which was the use specified by the petitioner. Since EPA registers formic acid as a pesticide to control Varroa and tracheal mites, their recommendation and this proposed rule would, in effect, allow the use of formic acid to control both Varroa and tracheal mites in organic apiculture.

At the October 2010 NOSB meeting, the NOP and NOSB discussed the placement of formic acid on the National List. The NOP raised the question of whether listing formic acid, a miticide, under § 205.603(b) is appropriate given that § 205.603(b) specifies that substances under this section be limited to use as "a topical treatment, external parasiticide (emphasis added) or local anesthetic as applicable". The NOSB explained that their research indicated that mites can be considered a parasite. The NOSB also stated that listing formic acid at § 205.603(b) would be consistent with the listing for sucrose octanoate esters, another substance in this National List section which is approved for use in apiculture to control Varroa mites. Through this proposed rule, the NOP is seeking comments on the placement of formic acid on the National List. Furthermore, the NOP may reconsider the placement of formic acid on the National List as part of any future rulemaking on organic apiculture standards. In the NOP's consideration of the addition of formic acid to the National List, the NOP would also like to reiterate that registered pesticide products intended for use in organic production and handling must also be evaluated for compliance with EPA's August 2004 list of inert ingredients, minus any revoked inert ingredients.

The Secretary has reviewed and proposes to accept the NOSB's recommendation. Consistent with the NOSB recommendation, this proposed rule would amend § 205.603 of the National List by adding formic acid (CAS # 64-18-6) at paragraph (b)(2) as a synthetic substance allowed for use as follows:

Formic acid (CAS # 64-18-6)—for use as a pesticide solely within honeybee hives.

Section 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

This proposed rule would amend § 205.605(a) of the National List regulations by adding the following substance:

Attapulgite. Attapulgite was petitioned for two uses: (1) as a nonsynthetic processing aid in organic handling for purifying vegetable and animal oils; and (2) as a livestock feed additive.[17] Attapulgite is the product of naturally occurring attapulgus clay that is mined and subsequently dried and pulverized into a fine bluish gray powder. Fine particle size and high porosity and surface area give attapulgite the capacity to absorb and adsorb various materials such as chlorophyll, metals and other impurities to improve the appearance, flavor and stability of plant and animal oils. The clay is added to heated liquid oil, stirred, and filtered out of the oil. According to the petitioner, adverse effects to human health would not be expected from occupational exposure to this product

[17] Due to the nonsynthetic classification of this substance, a petition for use as an additive for organic livestock feed is not required.

through inhalation or ingestion when proper protective equipment is utilized.[18] The FDA has listed this substance in the database, Everything Added to Food in the United States (EAFUS) (Doc. No. 1943) and references this substance among those generally regarded as safe in 21 CFR Part 582.99 when used as an adjuvant for pesticide chemicals. The EPA permits attapulgite as an inert ingredient eligible in minimum risk pesticides applied for food and non-food uses which are exempt from federal registration under Section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The EPA has determined that attapulgite is exempt from the requirement of a tolerance when used as an inert ingredient in pesticide formulations applied pre- and post-harvest per 40 CFR 180.910.[19]

At its April 26-29, 2011, meeting in Seattle, WA, the NOSB recommended adding attapulgite to the National List for use as a processing aid in organic handling of plant and animal oils. The NOSB did not receive public comments against this recommendation. During their deliberations, the NOSB noted that bentonite, a material already on the National List which can serve a similar bleaching function as attapulgite, requires acid activation. The NOSB explained that, though acid activation can be used to enhance bleaching properties of attapulgite, acid activation is not required for the substance to function as a processing aid and, therefore, may be preferable to the use of bentonite. The NOSB did not, however, recommend restricting the use of attapulgite to non-acid activated forms. During this public meeting, the NOSB evaluated attapulgite

[18] The petition was submitted by the Oil-Dri Corporation of America, and is retrievable from the NOP website in the Petitioned Substances Database: http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase.

[19] Technical Report on Attapulgite. February 1, 2010. A copy of this report is available in the petitioned substances database, http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase.

against the evaluation criteria of 7 U.S.C. 6517 and 6510 of the OFPA, received public comment, and concluded the substance is consistent with the OFPA evaluation criteria. Based upon the evaluation criteria, public comment, and the petitioner's request, the NOSB issued a final recommendation to add attapulgite to the National List.

The Secretary has reviewed and proposes to accept the NOSB recommendation. Consistent with the NOSB recommendation, this proposed rule would amend § 205.605(a) of the National List by adding attapulgite as follows:

Attapulgite—as a processing aid in the handling of plant and animal oils.

III. Related Documents

Two notices were published regarding the meetings of the NOSB and deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations included in this proposed rule were announced for NOSB deliberation in the following Federal Register notices: (1) 76 FR 12013, March 4, 2011, (Attapulgite and Tetracycline); (2) 75 FR 57194, September 20, 2010, (Formic acid).

IV. Statutory and Regulatory Authority

The OFPA, as amended [7 U.S.C. 6501 et seq.], authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k) and 6518(n) of the OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under § 205.607 of the NOP regulations. The

current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP Web site at http://www.ams.usda.gov/AMSv1.0/nop.

A. Executive Order 12866

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

B. Executive Order 12988.

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in § 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under §§ 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to § 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State

under certain circumstances. Such additional requirements must: (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to § 2120(f) of the OFPA (7 U.S.C. 6519(f)), this proposed rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C. 1031-1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), nor the authority of the Administrator of EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or

erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, the AMS performed an economic impact analysis on small entities in the final rule published in the Federal Register on December 21, 2000 (65 FR 80548). The AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this proposed rule would not be significant. The effect of this proposed rule would be to allow the use of additional substances in agricultural production and handling. This action would relax the regulations published in the final rule and would provide small entities with more tools to use in day-to-day operations. The AMS concludes that the economic impact of this addition of allowed substances, if any, would be minimal and beneficial to small agricultural service firms. Accordingly, USDA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than $7,000,000 and small agricultural producers are defined as those having annual receipts of less than $750,000.

Based on USDA data from the Economic Research Service (ERS), the U.S. organic sector included nearly 13,000 certified organic crop and livestock operations at

the end of 2008. These operations contained more than 4.8 million certified acres consisting of 2,665,382 acres of cropland and 2,160,577 acres of pasture and rangeland. The total acreage under organic management represents a twelve percent increase from 2007.[20] AMS believes that most of the certified production and handling operations would be classified as small entities under the criteria established by the SBA.

The U.S. sales of organic food and beverages have grown from $3.6 billion in 1997 to nearly $21.1 billion in 2008.[21] Between 1990 and 2008, organic food sales have historically demonstrated a growth rate between 15 to 24 percent each year. In 2010, organic food sales grew 7.7%.[22]

In addition, USDA has accredited 93 certifying agents who provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP web site, at http://www.ams.usda.gov/nop. AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA.

D. Paperwork Reduction Act.

No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

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[20] U.S. Department of Agriculture, Economic Research Service, 2009. Data Sets: *U.S. Certified Organic Farmland Acreage, Livestock Numbers and Farm Operations, 1992-2008. http://www.ers.usda.gov/Data/Organic/.*

[21] Dimitri, C., and L. Oberholtzer. 2009. *Marketing U.S. Organic Foods: Recent Trends from Farms to Consumers*, Economic Information Bulletin No. 58, U.S. Department of Agriculture, Economic Research Service, *http://www.ers.usda.gov/Publications/EIB58*.

[22] Organic Trade Association's *2011 Organic Industry Survey.* Available at: http://www.ota.com.

E. Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

F. General Notice of Public Rulemaking.

This proposed rule reflects recommendations submitted by the NOSB to the Secretary to amend the annotation for one substance and to add two substances on the National List. A 60-day period for interested persons to comment on this rule is provided and is deemed appropriate.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, Subpart G is proposed to be amended as follows:

PART 205 – NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority**:** 7 U.S.C. 6501 – 6522.

2. Section 205.601 paragraph (i)(12) is revised to read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

(i) *** * ***

(12) Tetracycline, for fire blight control in apples and pears only until October 21, 2014.

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3. Section 205.603 is amended by:

A. Redesignating paragraphs (b)(2) through (b)(7) as paragraphs (b)(3) through (b)(8); and

B. Adding new paragraph (b)(2) to read as follows:

§ 205.603 Synthetic substances allowed for use in organic livestock production.

* * * * *

(b) *** * ***

(2) Formic acid (CAS # 64-18-6)—for use as a pesticide solely within honeybee hives.

* * * * *

4. In § 205.605(a), the substance "Attapulgite" is added in alphabetical order to read as follows:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))."

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(a) * * *

Attapulgite—as a processing aid in the handling of plant and animal oils.

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Dated: November 1, 2011

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Acting Administrator
Agricultural Marketing Service

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